

REMARKS

Claims 1-17, 57, and 109-124 are now pending. Claims 57 and 109-112 are cancelled herein and have been represented as claims 125-129. Claims 1, 17, and 113 have been amended and additionally, claims 114-124 have been amended to properly depend from renumbered claims 113-124. Claims 130-133 are new.

Applicants note that Claim 57 was inadvertently cancelled in the Amendment dated December 12, 2002. However, as indicated in the cover sheet and text of the Office Action, Claim 57 has been examined. For clarity, Applicants have herein cancelled claim 57 and claims 109-112 dependent thereon and represented these claims as claims 125-129.

No new subject matter has been added, and the amended and new claims should not necessitate an additional search. Support for the amended and new claims can be found in the application and claims as originally filed. Support for those amendments that cannot be found directly in the claims as filed can be found in the specification. For example, support for the amendments to the claims regarding the recitation of a “decaying waveform” can be found on page 8, lines 11-28 of the specification and in the figures. See for example, Figures 1.4-1.5 and 18A-E, which present examples of decaying waveforms in accordance with embodiments of the present invention as well as the examples presented on page 29, line 31 - page 31, line 18 of the specification. Support for new claims 130-133 regarding a waveform that decays in a certain number of seconds can be found on page 8, lines 15-16 of the specification.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

Applicants thank the Examiner for renumbering added claims 110-125 to comply with 37 C.F.R. § 1.126. Applicants acknowledge that these claims are now numbered 109-124.

The Claims Comply with 35 U.S.C. §102

Rejection of Claims 1-3, 5-8, 10-13, 17, 57, 109-121, 123 under 35 U.S.C. 102(b)
(Taylor et al US 5,192,507)

Claims 1-3, 5-8, 10-13, 17, 57, 109-121, 123 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Taylor et al. (US 5,192,507). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The standard for anticipation is that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 as amended recites detecting a **transient electrical signal giving rise to a decaying waveform** that is produced by a monodirectional movement of a first molecule through a conducting medium sample relative to an immobilized second molecule and relating the detected transient electrical signal to at least one characterizing feature of the first molecule and second molecule in the sample. [Emphasis added]. Claim 57 represented as Claim 125 recites detecting a **transient electrical voltage giving rise to a decaying waveform** that is produced by a binding event between a first molecule and an immobilized second molecule and relating the detected transient electrical voltage to the occurrence of the binding event between the first and second molecule. [Emphasis added].

Taylor et al. do not teach a transient electrical signal giving rise to a decaying waveform but instead detect an electrical signal that is produced by changes in the alternating current impedance of a biosensor (column 7, lines 27-38). The Office Action asserts that Taylor et al. “teaches the detection of a transient electrical signal produced by a binding event and relating the signal to the occurrence of the binding event”. However, the receptor-based sensor of Taylor et al. detects an electrical signal that is not transient

and arises from a change in an external stimulus (column 7, line 11 – column 8, line 30). Taylor et al. teach that “an alternating current field across the electrodes is used to detect binding of substances (analyte of interest) to the immobilized receptors” (column 7, lines 27-29) and that “binding of the receptor and analyte of interest occurs, producing changes in the alternating current impedance of the biosensor” (column 7, lines 33-35). Taylor et al. do not teach the transient electrical signal of the present invention nor how to detect it. The detected electrical signal of Taylor et al. is based on a change in an alternating current impedance, which is a steady state signal and therefore not a measurement of an electrical signal that is transient. The present invention relates to a detection of a “transient electrical signal of interest that is not a steady state signal” (page 8, line 17). In contrast to the invention of Taylor et al., the detected electrical signal of the present invention is transient, arising from a potential that is created from within the system and giving rise to a decaying waveform (see, for example, page 8, line 29 – page 9, line 11 and Figures 1.1-1.5 of the specification). Taylor et al. do not apparently contemplate detecting a transient electrical signal that gives rise to a decaying waveform.

Claims 2-3, 5-8, 10-13, 17, 109-121, and 123 are dependent on either claim 1 or claim 57. As discussed above, claim 1 and claim 57 represented as claim 125 are not anticipated by Taylor et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Taylor et al. Accordingly, Applicants submit that Taylor et al. do not anticipate the pending claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-5, 7-13, 15, 57, 109-121, and 123 under 35 U.S.C. 102(b)
(Lennox et al US 5,955,379)

Claims 1-5, 7-13, 15, 57, 109-121, and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Lennox et al. (US 5,955,379). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The subject matter of claim 1 and claim 57 represented as claim 125 is described above. Lennox et al. teach a biosensor apparatus that detects a binding event between a ligand and a receptor by detecting ion-mediated electron flow. Contrary to the present invention, however, Lennox et al. do not teach that the detected electrical signal relating to a binding event between a ligand and a receptor is transient and gives rise to a decaying waveform over time as is taught by the present invention. See, for example, Figures 7 and 9 of Lennox et al. As asserted in the Office Action, “binding of a receptor to the monolayer-bound ligand, and the resultant perturbation of the monolayer structure, causes ion-mediated electron flow across the monolayer” in the disclosure of Lennox et al. The detected electrical signal of the present invention, however, does not arise from ion-mediated electron flow caused by a perturbation in a monolayer structure resulting from a binding event. Rather, the detected electrical signal of the present invention relates to the movement of one molecule toward an immobilized second molecule resulting in a binding event, which movement generates a detectable electrical signal that is transient and gives rise to a decaying waveform (see, for example, page 36, line 31 – page 37, line 5 and Figure 11 of the specification). Lennox et al. do not teach the limitation of detecting a transient electrical signal that gives rise to a decaying waveform as is taught by the present invention. Therefore, Lennox et al. do not anticipate the claimed invention.

In addition, claims 2-5, 7-13, 15, 109-121, and 123 are dependent on either claim 1 or claim 57. As argued above, claim 1 and claim 57 represented as claim 125 are not anticipated by Lennox et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Lennox et al. Accordingly, Applicants submit that Lennox et al. do not appear to anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-4, 7, 8, and 13-16 under 35 U.S.C. 102(b) (Lowe, An introduction to the concepts and technology of biosensors, 1985, Biosensors, 1, 3-16)

Claims 1-4, 7, 8, and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe (Lowe, An introduction to the concepts and technology of biosensors, 1985, Biosensors, 1, 3-16). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The subject matter of claim 1 is described above. Lowe teaches the use of a biosensor comprising a biologically sensitive material immobilized in intimate contact with a suitable transducing system, which converts the biochemical signal into a quantifiable and processable electrical signal. Lowe does not teach what a suitable transducing system is, nor how to convert the biochemical signal into a quantifiable and processable electrical signal. Significantly, Lowe does not teach the use of transient electrical signals nor how to detect such transient electrical signals. Lowe therefore does not teach the claimed limitations of the present invention.

In addition, claims 2-4, 7, 8, and 13-16 are dependent on claim 1. As discussed above, claim 1 is not anticipated by Lowe. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claim 1 are thus not anticipated by Lowe. Accordingly, Applicants submit that Lowe does not appear to anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-3, 5, 7-13, 15, 57, and 109-124 under 35 U.S.C. 102(e)
(Henkens et al US 6,391,558)

Claims 1-3, 5, 7-13, 15, 57, and 109-124 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al. (US 6,391,558). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The subject matter of claim 1 and claim 57 represented as claim 125 are described above. Henkens et al. teach an electrochemical detection system in which a biochemical reaction generates a measurable current when an amperometric potential is applied.

Henkens et al. do not teach the claimed limitation of a transient electrical signal that gives rise to a decaying waveform. Henkens et al. instead teach the detection of an electrical signal by measuring a change in an applied potential over time, which change does not give rise to a decaying waveform. See, for example, Figure 7; column 11, lines 11-26; and column 37, line 1 – column 38, line 54 of Henkens et al. As is recited in claims 1 and 125 as amended and supported in the specification and figures, the present invention detects a transient electrical signal giving rise to a decaying waveform that is generated independent of an external stimulus such as the applied potential of Henkens et al. (see, for example, page 29, line 11 – page 31, line 18 of the specification and Figures 17 and 18). Henkens et al. therefore do not teach the claimed limitations of the present invention.

In addition, claims 2-3, 5, 7-13, 15, and 109-124 are dependent on either claims 1 or 57. As argued above, claim 1 and claim 57 represented as claim 125 are not anticipated by Henkens et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Henkens et al. Accordingly, Applicants submit that Henkens et al. do not appear to anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

For the reasons stated above, Applicants submit that the claimed invention is not anticipated by the cited art. Applicants submit that none of the cited references teach detecting a transient electrical signal giving rise to a decaying waveform as recited in the claims and taught in the specification, for example in Figures 1.4-1.5 and 18A-E. Accordingly, Applicants respectfully request reconsideration and withdrawal of the §102 rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the pending claims are in condition for allowance, and early and favorable reconsideration is respectfully solicited.

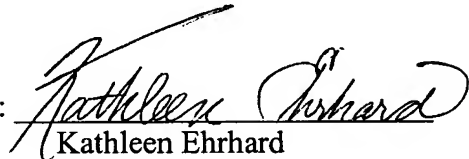
If there are any other fees due in connection with the filing of this Response, please charge the fees to our **Deposit Account No. 18-1945** under Order No. SUPP-P01-012.

Respectfully submitted,

Date: May 18, 2004

Customer No: 28120
Ropes & Gray LLP
One International Place
Boston, MA 02110
Telephone: (617) 951-7000
Facsimile: (617) 951-7050

By:


Kathleen Ehrhard
Reg. No. 55,144